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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,676	10/16/2001	Eija Marjut Pirhonen	01942-00003	6631

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EXAMINER

THOMPSON, CAMIE S

ART UNIT	PAPER NUMBER
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1/74

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/981,676	PIRHONEN, EIJA MARJUT	
	<b>Examiner</b>	<b>Art Unit</b>	
	Camie S Thompson	1774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on RCE filed September 9, 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13, 14 and 25-28 is/are allowed.
- 6) ☒ Claim(s) 1-12, 15-22, 29-33 and 35-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 9, 2004 has been entered.
2. Applicant's amendment and accompanying remarks filed September 9, 2004 have been acknowledged.
3. Examiner acknowledges amended claims 1, 6, 13, 14, 25, 27 and 28.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-12, 15-24 and 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al., U.S. Patent Number 4,655,777.

Dunn discloses a porous composite material comprising sintered bioactive ceramic fibers as per instant claims 1-5, 17-18 and 23-24 (see column 5, lines 65-68 and column 6, lines 60-61). The reference also discloses that the fibers are encased in a matrix of a polymer such as poly(L-lactide) as per instant claims 6-8 (see reference claim 1). Dunn also discloses that the fibers were

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cut in 2-inch lengths and have a diameter from .074 mm - .559 mm as per instant claims 15-16 and 19-20 (see column 8, lines 41-54). Column 11, lines 1-23 of the reference discloses that a poly(DL-lactide film can be attached to the composite material as per instant claims 31-33. The phrase "capable of promoting bone regeneration" in instant claim 34 does not provide a positive recitation to the claim. The reference discloses sintered ceramic fibers as recited in the instant claims. Therefore, it would be expected that the sintered fibers would be capable of promoting bone regeneration.

Dunn does not disclose the thickness of the coating and the porosity of the composite material as per instant claim 1, 9-10 and 21-22. The thickness of the coating protects the fibers. Discovery of optimum values of a result effective variable involves only routine skill in the art in re Boesch, 617 F.2. 272, 205 USPQ 215 (CCPA). Therefore, it would have been obvious to one of ordinary skill in the art to have a coating on the bioactive glass fibers from about 1 micron to 200microns in order to prevent breakage of the fibers. The bioactive fibers disclosed in the reference are highly porous as shown in column 2, lines 67-68. Therefore, it would be expected that the porosity of the composite comprising the bioactive fibers would be between 5 to 95 volume percent.

Claims 3-5, 11-12 and 35-37 are product by process claims. Even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product by process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process. See MPEP 2113.

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6. Claims 13-14 and 25-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Response to Arguments*


7. Applicant's arguments filed September 9, 2004 have been fully considered but they are not persuasive. Applicant argues that the Dunn reference fails to teach or suggest glass or ceramic fibers sintered together to form a scaffold. The Dunn reference discloses fibers that include ceramic powders and a biodegradable glass. The reference also discloses ceramic materials such as  $\beta$ -TCP (see column 5, lines 65-68) are formed into fibers wherein the fibers are sintered together (see column 6, lines 60-61). The Dunn reference teaches ceramic fibers that are sintered together, as does applicant. Applicant admits that Dunn teaches sintering ceramic materials to make reinforcing fibers. The fibers are sintered together in the Dunn reference, as in the instant claims. Additionally, applicant argues that the Dunn reference does not disclose the porosity. Although Dunn does not disclose the specific porosity, the reference does disclose the use of ceramic fibers that are highly porous. Also, the porosity is an optimizable feature. The reference discloses that the use of ceramic fibers produces a highly porous material. It would be obvious to one of ordinary skill in the art to have the porosity of the material be in the range of 50 to 95 volume percent. Applicant argues that the polymer completely encases the fibers in the Dunn reference and would provide for little or no porosity. Applicant claims glass or ceramic fibers that are sintered together. The Dunn reference teaches ceramic fibers that are sintered

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together. The reference also discloses that the ceramic material (fibers) is highly porous. The Dunn reference reads on the limitations of the instant claims. The rejection is maintained.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Camie S. Thompson whose telephone number is (571) 272-1530. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena L Dye, can be reached at (571) 272-3186. The fax phone number for the Group is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RENA DYE  
SUPERVISORY PATENT EXAMINER 10/22/04  
A.U. 1774